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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/659,570

09/09/2003

Martin Morrissey

MCA-616 US

5746

25182 7590 10/16/2007
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BILLERICA, MA 01821

EXAMINER

MCKANE, ELIZABETH L

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

10/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/659,570

Applicant(s)

MORRISSEY ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-13 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-13 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Claim Rejections - 35 USC § 112

1. Claims 1, 5, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "slight" is a relative term which renders the claim indefinite. The term "slight" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 6, and 8-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Padgett (US 4,644,586) or Trewella et al. (US 3,073,507).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines 19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed **38**

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adjacent the interface between the first and second portions to create a sealed, sterile portion.

See col.4, lines 10-38; Figures 4-6.

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15. The intended use of the device does not structurally limit the bag in any patentable sense.

As to the recitation of the contents of the bag, it has been held that “expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, “[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims.” See *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Furthermore, as to the contents and the second section being under a vacuum or positive pressure, these limitations are directed to the ultimate intended use of the device and do not limit the bag in any structural manner.

As to claims 5 and 6 and the limitations wherein “the bag and its contents being under a slight vacuum” and “the bag and its contents being under a slight positive pressure” are not considered to be structurally limiting on the bag but are intended uses of the bag.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 7, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trewella et al. in view of McDonald (US 6,030,578).

Trewella et al. is silent with respect to a closed collar or port attached to the non-porous section. McDonald, however, discloses a container **201** for sterilizing and transferring articles to a sterile enclosure. The container includes a collar **202** for attachment to a sterile enclosure during transferring of the sterilized articles. This collar is certainly capable of use as a pressure or vacuum port, as well. Since the bag of Trewella et al. is disclosed for use in the sterilization of medical articles, it would have been obvious to use the bag of Trewella et al. in the sterile environment of McDonald and when doing so, to provide a collar for connection to the enclosure.

6. Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Padgett or Trewella et al., both in view of Massage (US 3,837,215).

Padgett teaches a bag **10** having a first porous section **14** and a second non-porous section **12**, the two sections in registry with each other. The porous section may be a nonwoven (col.2, lines 55-57) and the non-porous section may be an SMS polypropylene (polyolefin) laminate having a barrier coating applied thereto (col.3, lines 19-22). After sterilization (steam or ETO), the contents **28** of the bag are moved to the second non-porous section **12** and bag is sealed **38**

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adjacent the interface between the first and second portions to create a sealed, sterile portion.

See col.4, lines 10-38; Figures 4-6.

Trewella et al. teaches a bag **10** having a first porous section **13** and a second non-porous section **11**. The porous section of the bag may be paper (nonwoven) and the nonporous section may be a film of polyethylene, a polyolefin. See col.3, lines 14 and 50-64. After steam sterilization the bag may be sealed at an interface **21** between the first and second sections. See Figures 6 and 10; col.4, line 71 to col.5, line 15.

Neither Padgett nor Trewella et al. disclose a step of applying a vacuum or a positive pressure to the second section during or after the formation of the second seal. Massage discloses a method of integrity testing of sealed containers. The containers may be flexible packages/bags (col.1, lines 6-18) and are tested under a vacuum or positive pressure holding after being sealed. See col.3, lines 51-57. As Massage discloses that integrity testing assures that the packages are adequately sealed from contaminants and as both Padgett and Trewella et al. teach sealing the sterilized contents from contaminants, it would have been obvious to employ the method of Massage to test the integrity of the seal of the second section.

Response to Arguments

7. Applicant's arguments filed 30 July 2007 have been fully considered but they are not persuasive.

8. Specifically, with respect to the anticipation of claims 1, 5, 6, and 8-12 by Padgett and Trewella et al., applicant argues that neither Padgett nor Trewella et al. disclose maintaining the second section in a condition of a vacuum or positive pressure. However, as set forth in the

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rejection, this type of limitation is no more than an intended use of the bag and does not structurally limit the invention.

Conclusion

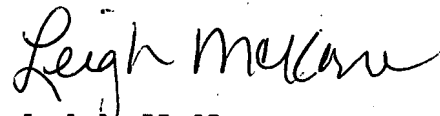
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

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like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leigh McKane
Primary Examiner
Art Unit 1797

elm
13 October 2007